



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,206	12/12/2000	Ron Plass	C-331	4543

7590 04/11/2003

Stuart E. Krieger
c/o Bristol-Myers Squibb Company
100 Headquarters Park Drive
Skillman, NJ 08558

EXAMINER

KIDWELL, MICHELE M

ART UNIT	PAPER NUMBER
----------	--------------

3761

DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,206

Applicant(s)

PLASS ET AL.

Examiner

Michele Kidwell

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on December 13, 1999. It is noted, however, that applicant has not filed a certified copy of the 9929517.2 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because:

- Reference character "24" has been used to designate both a cylindrical wall and an outer wall

- Reference character "26" has been used to designate both a cylindrical wall and an inner wall
- Reference character "50" has been used to designate both a surface, a seat surface, a seal seat surface and a seal seat

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- Reference number "52" is not shown in the drawings

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 – 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a curved seal seat surface, does not reasonably provide enablement for a seal seat surface that curves through about 90 degrees. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 14 – 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an annular flange, does not reasonably provide enablement for an apertured flange. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1 – 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5 – 6, 13 – 14 and 18 recite the limitation "the form of" in lines 10, 5, 10, 8, 6 and 5 of each claim respectively. There is insufficient antecedent basis for this limitation in the claims.

Further, with respect to claims 1, 5 – 6, 13 – 14 and 18, the applicant claims that a deformable member is "in the form of, or behaving substantially as a split ring". This language is vague and unclear. The language reads as if the member may not be a split ring, however, no other comparable device has been disclosed. Further, the applicant uses the word substantially, yet it is unclear to what degree a device may be considered to behave as a split ring. Correction and/or clarification are required.

As to claim 2, it is unclear how a surface can curve through (emphasis added) about 90 degrees. A surface may curve a certain degree, but how does it curve through a degree? Correction and/or clarification are required.

Claim 3 recites the limitation "the plane" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the channel floor" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 7, the use of the word "it" in line 2 renders the claim indefinite because it is not clear what "it" is being used to refer to. Correction is required.

With reference to claims 11 and 12, the applicant claims "a natural shape". This term has not been supported by the specification and it is unclear what the applicant intends to encompass with this term. Further, the use of the word "it" in line 2 of each claim renders the claims indefinite because it is not clear what "it" is being used to refer to. Correction is required.

Claim 13 recites the following limitations:

- "the width of the channel" in line 5
- "the channel floor" in line 6
- "the tapered first wall" in lines 10 – 11
- "the locking ring" in line 12

There is insufficient antecedent basis for these limitations in the claim.

Claim 16 recites the limitation "the profile" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 9, 11 – 15 and 18, as best understood by the examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen (US 5,496,297).

With respect to claim 1, Olsen discloses an ostomy coupling fastenable by a deformable locking member, the coupling comprising a first coupling member comprising a deflectable seal wing extending around a coupling aperture of the first coupling member; a second coupling member comprising a seal seat surface extending around a coupling aperture of the second coupling member, the seal seat surface tapering with a curved taper in a direction towards the first coupling member when the coupling members are in an assembled condition; and a deformable locking member being carried on one of the coupling members for releasably fastening the coupling members together wherein, in use, when the coupling members are in said assembled condition, the deflectable seal wing is deformed into a curvature to bear against the curved taper of the seal seat surface as set forth in col. 3, lines 25 – 46 and figure 1.

With reference to claim 2, Olsen discloses an ostomy surface wherein the seal seat surface curves as set forth in figure 2.

As to claim 3, Olsen discloses an ostomy coupling wherein the seal seat surface curves from a first direction generally parallel to the plane of the second coupling member to a second direction generally perpendicular to the plane as set forth in figures 1 and 2.

Regarding claim 4, Olsen discloses a seal seat surface that curves generally uniformly over a major portion of the seal seat surface as set forth in figure 2.

As to claims 5 and 6, see the rejection of claim 1, col. 7, lines 18 – 50 and figure 5.

With reference to claims 7 – 9 and 11 – 12, see figure 2.

As to claim 13, see the rejection of claim 1 and col. 8, lines 45 – 59.

With respect to claims 14 – 15 and 18, see figure 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 16 – 17 and 19 – 20, as best understood by the examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen (US 5,496,297).

The difference between Olsen and claims 10 and 17 is the provision that the ostomy coupling comprises a plurality of spaced apart channel portions or apertures.

It would have been obvious to one of ordinary skill in the art to modify the channel portion of Olsen to provide a plurality of channel portions or apertures since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art.

As to claims 16 and 19, absent a critical teaching and/or unexpected result, the examiner contends that the claimed limitation would have been an obvious matter of design choice that does not patentably distinguish the claimed invention from the prior art.

The difference between Olsen and claim 20 is the provision that the ostomy coupling comprises a plurality of locking projections and wall segments.

It would have been obvious to one of ordinary skill in the art to modify the locking projection and wall segment of Olsen to provide a plurality of such since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 703-305-2941. The examiner can normally be reached on Monday - Friday, 7:30am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Art Unit: 3761

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Michele Kidwell

Michele Kidwell

April 1, 2003

Wei Lun Lo

WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700